K110998

OCT 25 2011

510(k) SUMMARY: AFFIRM™ VCF System

Company: Algea Therapies
2560 General Armistead Avenue
Audubon, PA 19403
(610) 930-1800

Contact: Kelly J. Baker, Ph.D
Vice President, Regulatory and Clinical Affairs

Date Prepared: May 26, 2011

Device Name: AFFIRM™ VCF System

Classification: Per 21CFR as follows:
§888.1100: Arthroscope
§888.3027: Cement/Bone Vertebroplasty
Product Code: HRX, NDN
Regulatory Class: II, Panel Code: 87

Predicate(s): KyphX® Inflatable Bone Tamps (K041454)
SE date: September 30, 2005

Purpose:
The purpose of this submission is to request clearance for the AFFIRM™ VCF System.

Device Description:
The AFFIRM™ Inflatable Bone Tamp is a bone tamp with an inflatable balloon attached to the distal end, designed to create a void in cancellous bone. The Inflatable Bone Tamp is a sterile, single-use device manufactured from polyurethane.

The system also contains access instruments (including drills, cannulas, jamshidi needles, and K-wires), biopsy needle, cavity preparation instruments (expanding scraper), sleeve, an inflation device, and cement delivery instruments (cement mixer, cement guns, and filler delivery needles).

Indications for Use:
The AFFIRM™ VCF System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. Vertebral compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancer and myeloma. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements

indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

Performance Data:
The AFFIRM™ VCF System meets the specification and performance characteristics and is substantially equivalent to the predicate devices. The testing that was conducted included functional testing, such as fatigue insertion and withdraw, inflation, burst, and bond strength.

Biocompatibility testing confirmed that the AFFIRM™ VCF System components are biocompatible and meet the applicable requirements of the FDA Blue Book Memorandum G95-1: *Use of International Standards ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.*

Basis for Substantial Equivalence:
The AFFIRM™ VCF System is substantially equivalent to the legally marketed predicate KyphX Inflatable Bone Tamps in terms of intended use, technological characteristics, safety, and effectiveness. The products have the same fundamental scientific technology, basic design, functional characteristics and the same clinical applications. The AFFIRM™ VCF System does not raise any new concerns of safety and efficacy when compared to the legally marketed predicate device. Therefore, the AFFIRM™ VCF System is substantially equivalent to the existing predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 25 2011

Algea Therapies
% Kelly J. Baker, Ph.D.
Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K110998
Trade Name: AFFIRM™ VCF System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: September 20, 2011
Received: September 21, 2011

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____

Device Name: AFFIRM™ VCF System

Indications:

The AFFIRM™ VCF System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. Vertebral compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancer and myeloma. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

Prescription Use __X__ OR Over-The-Counter Use____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110998